DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 18, 2014

GE Medical Systems LLC
% Mr. Huy Doan
Regulatory Affairs Director, MICT
GE Healthcare
3000 N. Grandview Blvd.
WAUKESHA WI 53188

Re: K141477
Trade/Device Name: Discovery IQ
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: August 25, 2014
Received: August 26, 2014

Dear Mr. Doan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

k141477

Device Name

Discovery IQ

Indications for Use *(Describe)*

GE Discovery IQ PET/CT system is intended for head and whole body attenuation corrected Positron Emission Tomography (PET) imaging and localization of emission activity in patient anatomy by means of integrated PET and CT images.

The system is to be used by trained health care professionals for imaging the distribution of radiopharmaceuticals in the body for the assessment of metabolic (molecular) and physiologic functions in patients of all ages. This can assist in the evaluation, diagnosis, staging, restaging, and follow up of lesions, disease and organ function such as (but not limited to) cancer, cardiovascular disease, and brain dysfunction. This device can also assist in radiotherapy planning.

The system can also be used as a stand-alone head and whole body multi-slice computed tomography (CT) diagnostic imaging systems.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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GE Healthcare

510(k) Summary of Safety and Effectiveness (in accordance to 21 CFR 807.87(h))

Device Name

Proprietary Device Name: Discovery IQ
Date prepared: June 3, 2014

Establishment Name and Registration Number of Submitter

Name: GE Medical Systems LLC
Registration Number: 2126677
Corresponding Official: David Duersteler
GE Healthcare
P.O. Box 414
Milwaukee, WI 53201
Phone: 262-312-7029
Email: david.duersteler@med.ge.com

Device Classification

Classification Code: 90 KPS
Panel Identification: Radiology
Classification Name: Emission Computed Tomography System (Per 21CFR 892.1200)
Common Name: PET/CT Imaging System
Classification Class: Class II Product
Reason for 510(k) Submission: Modified device

Device Description

The Discovery™ IQ consists of a fully integrated 3D Positron Emission Tomography and multi-slice Computed Tomography scanner with all available CT diagnostic applications, except gantry tilt. The PET detector is scalable offering 2 through 5 detector rings. Due to the overall length of the PET/CT, the patient table sits on a special base that drives the table between the PET and CT portions of the gantry. The PET/CT table is rated for a patient weight of 227 Kg (500 pounds) and the cradle travels up to 1700mm on standard systems, or up 2 meters on systems with the 2m scan range option.

Identification of Legally Marketed Equivalent Devices

Discovery PET/CT 710	GE Medical Systems LLC	K133657

Comparison with Predicate Devices

Both systems are PET/CT systems employ the same design, construction, materials, energy source, operating principles, and technology. Further, reconstruction algorithms are identical to existing methods including iterative reconstruction.

Both systems consist of a fully integrated 3D Positron Emission Tomography and multi-slice Computed Tomography scanner with all available CT diagnostic applications, except gantry tilt. Due to the overall length of the PET/CT, the patient tables sit on a special base that drives the table between the PET and CT portions of the gantry. The PET/CT table is rated for a patient weight of 227 Kg (500 pounds) and the cradle travels up to 1700mm on standard systems, or up 2 meters on systems with the 2m scan range option.

Both systems are compliant with the same IEC, NEMA and related safety and performance standards.

Both systems use the same acquisition methods and attenuation correction methods. All major functions and features have been previously marketed, and intended uses are the same. Discovery IQ performs as well as currently marketed devices, introduces no significant change in safety or effectiveness as compared to the predicate devices, and is therefore substantially equivalent in terms of safety and effectiveness to the currently marketed GE Healthcare Discovery PET/CT 710 product.

Indications for Use of Device

GE PET/CT systems are intended for head and whole body attenuation corrected Positron Emission Tomography (PET) imaging and localization of emission activity in patient anatomy by means of integrated PET and CT images.

The systems are to be used by trained health care professionals for imaging the distribution of radiopharmaceuticals in the body for the assessment of metabolic (molecular) and physiologic functions in patients of all ages. This can assist in the evaluation, diagnosis, staging, restaging, and follow up of lesions, disease and organ function such as (but not limited to) cancer, cardiovascular disease, and brain dysfunction. These devices can also assist in radiotherapy planning.

The systems can also be used as a stand-alone head and whole body multi-slice computed tomography (CT) diagnostic imaging systems.

Conclusion

In the opinion of General Electric Medical Systems, the GE Discovery IQ system is substantially the same in design, materials, energy sources, and technology, does not introduce new safety concerns, performs as well as currently marketed devices, and is therefore substantially equivalent in terms of safety and effectiveness to the currently marketed Discovery PET/CT 710 device. (K133657).

General Electric Company
P.O. Box 414
Milwaukee, WI 53201